

Applicant: Reiko M. Nakamura
Serial No.: 09877,802
Amendment dated December 3, 2003
Response to Office Action mailed September 3, 2003

In the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims

Claims 1-20 Cancelled

Claim 21. (Currently Amended) A transdermal delivery device for diagnosing infectious disease comprising,

an antigen composition and an antigen composition holding portion, wherein the antigen composition is applied to the holding portion for transdermal delivery of the antigen wherein the device is in contact with skin,

wherein the composition consists of an antigen and a physiologically effective solution consisting of phosphate buffered saline and a polyoxyethylene sorbitan derivative,

and wherein an immunogenic response is observed on the skin indicating the presence of active disease.

Claim 22. (Previously Presented) The device of Claim 21, wherein the antigen composition holding portion comprises a material selected from the group consisting of medical tape, medical plaster, gauze, a patch and a patch band.

Claim 23. (Currently Amended) The device of Claim 21, ~~wherein the antigen composition comprises an antigen and a physiologically effective solution,~~ wherein said physiologically effective solution promotes transdermal delivery of the antigen in an amount sufficient to generate an immune response.

Claim 24. (Previously Presented) The device of Claim 23, wherein the antigen is derived from a mycobacterial species selected from the group consisting of *Mycobacterium tuberculosis*, *Mycobacterium avium-intracellular*, *Mycobacterium*

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kansaii, Mycobacterium fortuitum, Mycobacterium chelonae, Mycobacterium leprae, Mycobacterium africanum, and Mycobacterium microti.

Claim 25. (Previously Presented) The device of Claim 23 wherein the antigen comprises a mycobacterial antigen.

Claim 26. (Previously Presented) The device of Claim 23, wherein the antigen is mycobacterial antigen selected from the group consisting of MPB44, MPB45, MPB51, MPB59, MPB64, MPB70, MPB80 and MPB83.

Claim 27. (Currently Amended) The device of Claim 23, wherein the antigen comprises MPB64 ~~and the physiologically effective solution comprises phosphate buffered saline and a surfactant.~~

Claim 28. (Currently Amended) The device of Claim 21, wherein the surfactant comprises a polyoxyethylene sorbitan ~~derivative~~ monooleate.

Claim 29. (Previously Presented) The device of Claim 21, wherein the infectious disease comprises tuberculosis.

Claim 30. (Previously Presented) The device of Claim 28, wherein the infectious disease comprises tuberculosis.

Claim 31. (New) The device of Claim 25, wherein the polyoxyethylene sorbitan derivative comprises polyoxyethylene sorbitan monooleate.

Claim 32. (New) The device of Claim 31, wherein the infectious disease comprises tuberculosis.

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Claim 33. (New) A transdermal delivery device for diagnosing infectious disease comprising,

an antigen composition and an antigen composition holding portion,
wherein the antigen composition is applied to the holding portion for transdermal
delivery of the antigen wherein the device is in contact with skin,

wherein the composition consists of a mycobacterial antigen and a
physiologically effective solution consisting of phosphate buffered saline and a
polyoxyethylene sorbitan monooleate,

and wherein an immunogenic response is observed on the skin indicating
the presence of active disease.